

REMARKS

Amendment to the Specification

Paragraph [0015] of the present specification has been amended to correct a clerical error. No new matter is introduced.

Claim Status

Claim 1 has been amended to recite that the amount of vacuum to be drawn is such that pressure differential between atmospheric pressure outside the tube and pressure within the tube is at least sufficient to allow a predetermined volume of said cells to be collected. Claims 14 and 27 have been amended similarly to recite that the collection container has an internal pressure less than atmospheric pressure outside the container. Support for these amendments is found in paragraphs [0015] and [0029] of the present specification.

Claims 7 and 20 have been amended to include “whole blood” as one of the cells or cell samples that are suitable for the present invention. Support for these amendments is found in paragraphs [0007], [0029] and [0031] of the present specification, wherein whole blood or normal blood is described as one of the cell or cell sample sources.

In addition, claims 1, 8-14 and 23-27 have been amended for formality reasons that are not related to patentability.

Pursuant to 37 C.F.R. §1.118(a), Applicant respectfully submits that the above amendments do not introduce any new material into the application. With these amendments, there are 27 claims pending, namely claims 1-27.

Restriction Requirement

In response to the Examiner’s restriction requirement, Applicant elects, with traverse, Group I, claims 1-11, directed to a method of making a collection device for cells, and claims 14-24, directed to a collection device for cells, for further examination.

The Examiner has alleged that the inventions of Groups I, II and III are distinct from each other. Applicant respectfully traverses the restriction requirement because these groups of claims are directed to patentably related and non-distinct inventions.

As the Examiner acknowledges, Groups I is related to Groups II and III as product and processes of use. There is a common thread that ties these groups together, that is,

a method or a collection device that are capable of maintaining cells in their original unaltered morphology and preserving cell antigenic sites for analysis. In particular, the method or collection device as the common technical feature in the present invention involves the use of less toxic and non-flammable reagent for fixing and stabilizing cells as well as the use of a collection container which has an internal pressure less than atmospheric pressure outside the container. Due to this common thread, Applicant believes that a search conducted for all of these groups would not be unduly burdensome.

For example, Group I encompasses a tube having an internal pressure less than atmospheric pressure outside the tube and containing an anticoagulant agent and a fixative agent that is less toxic and non-flammable, whereas Group II encompasses screening cells collected and preserved in such tube, and Group III encompasses preparing cells for analysis using such tube. It is apparent that the searches for Group I and Group II, or Group I and Group III can be coextensive.

As to Groups II and III, Applicant believes that they are not patentably distinct and that searches for use of the container for cell preparation as claimed in Group III and for use of the container for screening as claimed in Group II can be coextensive because preparation cells for analysis can be viewed as a pre-screening step.

In the event that the restriction requirement is not withdrawn, Applicant submits that the process claims of Groups II and III should be rejoined with the product claims of Group I and fully examined for patentability upon the allowance of the product claims in accordance with the provisions of MPEP §821.04.

In addition, the Examiner also requests that a single disclosed species be elected for prosecution on the merits to which the claims shall be restricted. In response, Applicant believes that the disclosed species are patentably related and non-distinct. However, in order to further the examination, Applicant elects the species of diazolidinyl urea (DU) from the group of fixative agents (subject matter of claims 1, 14 and 27); EDTA from the group of anticoagulants (subject matter of claims 2 and 15); whole blood from the group of cells and cell samples (subject matter of claims 7 and 20); and a packaging means for transporting said collection device from the group of additional components (subject matter of claims 10 and 23).

It is believed that the present election of species is made merely for the purpose of

giving the Examiner a starting point for examination and that any amendments to cancel the non-elected species are not necessary at this stage of the prosecution in accordance with MPEP 809.02(a), since no final decision has been made on the allowability of the generic claim(s). The claims that are readable upon the presently elected species are claims 1-11 and 14-24.

Furthermore, the Examiner requests a list of all copending applications that set forth similar subject matter to the present claims and a copy of such copending claims. Applicant submits that the present application is a non-provisional of U.S. provisional application Serial No. 60/418,978, filed October 16, 2002, which is now abandoned. There are no other copending applications in the U.S. at this time.

This document is being filed timely and no fee is believed to be due. However, should any fees be required for any reason, the Commissioner is authorized to deduct said fees from Howrey Deposit Account No. 01-2508/12642.0065.NPUS01.

Respectfully submitted,



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